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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,693	06/27/2000	Markus Pompejus	BGI-130CPRCE	4996

959 7590 11/20/2006

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EXAMINER
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HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/604,693

Applicant(s)

POMPEJUS ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,6,10-16 and 39-58 is/are pending in the application.
- 4a) Of the above claim(s) 49-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 10-16 and 39-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment of claims 1, 4, 39-41, 45-48 and the addition of new claims 49-58, in the paper 8/29/2006, is acknowledged. Claims 1, 4, 6, 10-16 and 39-58 are at issue and are present for examination.

Applicants' arguments filed on 8/29/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Newly submitted claims 49-58 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions corresponding to claims 1, 4, 39-41, 45-48 and the inventions corresponding to claims 49-58 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid can be used in other methods such as those used to mutate the encoded protein.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 49-58 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Information Disclosure Statement***

Applicants filing of the information disclosure statement filed on 8/29/2006 is acknowledged. Those references considered have been initialed.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4, 6, 10-16 and 39-48 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter. In the absence of the hand of man, naturally occurring nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). As previously stated, this rejection may be overcome by amending the claims to contain wording that specifies that the "full complement thereof" portion of the claim is an isolated molecule. The problem found in the current claims can be illustrated more clearly by looking at claims 40, 47 and 48, which are each drawn to "an isolated nucleic acid which encodes a polypeptide" or "a full complement thereof". While claims 1, 4, 6, 10-16, 39, 41-46 are not as clear as claims 40, 47 and 48, they also can be interpreted in a similar fashion as encompassing non-statutory subject matter.

In response to this rejection applicants have amended the claims and traverse the rejection as it applies to the newly amended claims. Applicants traverse the rejection on the basis that applicants submit that the pending claims do not encompass non-statutory subject matter, as the pending claims are directed to **isolated** nucleic acid molecules and "the full complement thereof." Applicants submit that based on the plain language of the claims, it is evident that the complement of an isolated nucleic acid

molecule would necessarily have to also be an isolated nucleic acid molecule. Applicants submit that based upon this, the claims do not encompass non-statutory subject matter.

Applicants further submit in support of applicants position claims from a number of issued U.S. Patents directed to subject matter.

Applicant's complete argument is acknowledged and has been carefully considered, however is found nonpersuasive for the reason previously stated and herein repeated.

As previously stated, this rejection may be overcome by amending the claims to contain wording that specifies that the "full complement thereof" portion of the claim is an isolated molecule. The problem found in the current claims can be illustrated more clearly by looking at claims 40, 47 and 48, which are each drawn to "an isolated nucleic acid which encodes a polypeptide" or "the full complement thereof". Applicant's statement that "the complement" of an isolated nucleic acid molecule would necessarily have to be an isolated nucleic acid is not convincing and unclear. Nothing in "the complement" dictates or necessitates "isolated". Thus the claims remain rejected for the reasons previously stated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', written over a horizontal line.

Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
11/2/2006